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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,894	06/19/2001	Daniel J. O'Sullivan	110.01290101	1710

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MUETING, RAASCH & GEBHARDT, P.A.  
P.O. BOX 581415  
MINNEAPOLIS, MN 55458

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/21/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/884,894**

Applicant(s)  
**O'Sullivan**

Examiner  
**Deborah Ware**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 12, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-15 and 20-42 is/are pending in the application.
- 4a) Of the above, claim(s) 8-15, 20-28, and 30-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 5
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 & 7 6) ☒ Other: **Notification: COPIES ORIGINALLY FILED**

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Claims 8-15 and 20-42 are pending.

The letter of Request For Correction Of Patent Application Publication filed on July 16, 2002 has been received and the paper will be addressed and processed, accordingly.

Further, the extension of 1 month of time is acknowledged. Furthermore, the Disclosure Statements filed March 29, 2002, and April 11, 2002, have been received and the fees charged to Applicants' designated deposit account(s). In addition the amendment filed April 11, 2002, has been received and considered.

1. Applicant's election with traverse of Group VI (claim 29) in Paper No. 12 is acknowledged. The traversal is on the ground(s) that no serious burden is presented and further because the case had already been searched in the first action. This is not found persuasive because each time the case comes before the examiner to be examined the case is searched and upon an attempt to update the initial search of each invention it was deemed necessary and prudent to restrict the claims into separate groups as it was a serious burden to the examiner to search all of the independent and distinct inventions presented. In attempt to provide Applicants' with a better quality examination and search the restriction was deemed necessary. Thus, although the case had been searched, such search in hindsight was a serious burden on the examiner and before proceeding with another action on the merits the examiner chose to set forth the restriction requirement. A telephone call was made on June 28, 2002, to request an oral election to the restriction requirement but did not result in an election being made possibly because the examiner was unable to make contact with Applicants' Representative. Therefore,

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this may be why Applicants' Representative is unaware of the telephone call of June 28, 2002. The request for rejoinder under 37 CFR 1.121 can be considered at the time allowable subject matter is indicated. Furthermore, it is possible that all groups may be rejoined depending upon the amendments and limitations Applicant may require once allowable subject matter has been determined.

The requirement is still deemed proper and is therefore made final.

2. Claims 8-15, 20-28 and 30-42 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 29 is examined on the merits.

3. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Bifidobacterium strains RecB1, strain RecB4, strain J1, strain J2, strain J4, strain P1, strain 6A or strain 10A, does not reasonably provide enablement for any and all strains of Bifidobacterium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out and practice the invention commensurate in scope with these claims. The unpredictability in the microbiological arts is very high and one of skill in the art would not be capable of predicting which

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Bifidobacterium strain produces a siderophore. Therefore, undue burden of experimentation would be necessary for one of skill to determine which Bifidobacterium strain capable of secreting a siderophore for use in a composition as claimed. Although methods of screening bacteria are conventional in the art, it is not conventional to screen for Bifidobacterium strains that secrete siderophores. Therefore, one of skill would not be capable of predicting the appropriate strain of Bifidobacterium for use in the claimed composition. Thus, the claim should be limited to the specific strains that secrete a siderophore as disclosed in the specification at page 7, lines 10-16. As evidence to support the unpredictability in the art the Yildirim reference cited below as art against the claim clearly teaches that not all strains of Bifidobacterium secrete or form siderophores (i.e. peptide compounds).

4. Claim 29 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yildirim et al, cited as the last reference on the enclosed PTO-1449 Form.

Claim is drawn to a composition comprising a Bifidobacterium that secretes a siderophore.

Yildirim et al. teach a food biopreservative comprising bacteriocin that are secreted by Bifidobacterium. Note the abstract and at page 47, col. 1, all lines, and also col. 2, all lines, also note on page 48, col. 1, all lines. A specific strain is disclosed as being the only one that secretes a siderophore. See Material and Methods, of page 47, col. 2, all lines. At page 48, clear zones of

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inhibition of other bacteria growth because of the presence of siderophore of the Bifidobacterium strain are noted.

The claim appears to be identical to the disclosure of the cited reference and is therefore, considered to be anticipated by the teachings therein. The identical composition is disclosed, however, in the alternative that there is some difference between the reference and the claimed subject matter due to some unidentified claimed characteristic for which is not disclosed then such difference is considered to be so slight as to render the claim *prima facie* obvious over the cited reference. It would have been obvious to one of ordinary skill in the art to provide a composition comprising a whole Bifidobacterium that secretes a siderophore as the reference clearly teaches that such strains thereof can produce or form siderophores which are peptide compounds that are detected by their ability to inhibit the growth of other bacteria. The reference clearly teaches such peptide compounds and the inhibition of growth of indicator strains which is by Applicant's own disclosure an indicator that a siderophore is produced or formed by Bifidobacterium. It is believed to be an inherent feature of the reference that the whole Bifidobacterium secretes a siderophore and this being taught by the reference that the same would be comprised by a composition as also taught by the cited reference. However, if there is a difference between the reference and the claimed subject matter regarding this feature then the whole bacterium in the composition would have been expected to secrete a siderophore as claimed herein. The claim in the alternative is at least *prima facie* obvious over the cited reference.

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5. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Nisbet et al. (US Pat. No. 5,340,577) cited on the enclosed PTO-1449 Form.

Claim is discussed above.

Nisbet et al. teach a composition comprising a Bifidobacterium that secretes a siderophore since the cited disclosure clearly teaches that Salmonella is inhibited by the composition of which contains Bifidobacterium. Therefore a siderophore is present in the composition. Note the abstract and col. 12, lines 65-69. All of the bacteria in the composition are taught to produce organic acids and bacteriosins but none of which would be effective against each other. However, the composition for which promotes production of a siderophore per se does inhibit the indicator strain Salmonella. Note col. 3, lines 30-57 and the inhibition is enhanced by a composition comprising Enterococcus and Bifidobacterium, note col. 4, lines 15-17.

The claim is identical to the disclosure of Nisbet et al. and is therefore, considered to be anticipated by the teachings therein. Secretion of a siderophore by Bifidobacterium is inherent to the teachings of the reference with respect to the enhanced inhibition of Salmonella wherein the composition comprises Bifidobacterium. Therefore, the Salmonella being an indicator strain disclosed by Applicant's own specification, page 6, lines 1-5, of which indicates a Bifidobacterium that secretes a siderophore, thus, the reference clearly teaches such bacterium that secretes a siderophore based upon the inhibition of Salmonella and the enhanced inhibition

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obtained when the probiotic composition comprises Bifidobacterium. Therefore, the siderophore is inherent to the teachings of the cited reference.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nisbet et al. in view of Yildirim et al., both discussed above.

Claim is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the composition as disclosed by Nisbet et al. comprising a Bifidobacterium strain that secretes a peptide compound (i.e. siderophore) as disclosed by Yildirim. The composition is clearly suggested by the combination of the cited references if not taught by the cited references individually. Clearly one of skill would have been motivated to provide for a composition comprising a Bifidobacterium that secretes a siderophore. A siderophore is clearly taught, or at least suggested, by the cited combination of references. The claims are at the very least prima facie obvious over the cited references applied as a combination.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware

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October 19, 2002

The papers filed on March 29, 2002 (certificate of mailing dated March 20, 2002) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS  
ORIGINALLY FILED

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If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.